The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JÜRG ZIMMERMANN, HANS-GEORG CAPRARO, PATRICIA IMBACH, and PASCAL FURET

Appeal No. 2002-1495 Application No. 09/051,827 MAILED

SEP 1 1 2003

U.S. PATENT AND TRADEMARK OFFICE Board of Patent Appeals and interferences

ON BRIEF

Before WINTERS, GRIMES, and GREEN, <u>Administrative Patent Judges</u>.
WINTERS, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 2, 3, 14, 16, 18, and 19. Claim 15 stands allowed. Claims 4, 6, and 17, which are the only other claims remaining in the application, stand objected to "as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims" (Paper No. 16, page 2).

Illustrative Claims

Claims 2, 3, and 19, which are illustrative of the subject matter on appeal, read as follows:

Claim 2. A compound of the formula I

$$(R_1)_q$$

$$R_2$$

$$R_3)_m$$

$$R_5$$

$$R_4$$

$$(R_3)_n$$

$$(R_3)_n$$

in which q is 1-5,

R₁ is halogen; lower alkyl; hydroxyl; lower alkanoyloxy; lower alkoxy which is unsubstituted or substituted by hydroxyl, lower alkoxy or carboxyl; a radical of the formula -O(-CH₂-CH₂-O)_t-R₆, in which t is 2-5 and R₆ is hydrogen or lower alkyl; carboxyl; lower alkoxycarbonyl; piperazin-1-yl-carbonyl; carbamoyl; N-lower alkyl-carbamoyl which is unsubstituted in the lower alkyl moiety or substituted by hydroxyl or amino; N,N-di-lower alkyl-carbamoyl; cyano; nitro; amino; lower alkanoylamino; lower alkylamino; N,N-di-lower alkylamino; aminosulfonyl or trifluoromethyl, where, if more than one radical R₁ is present in the molecule, these can be identical or different from one another, R₂ is hydrogen, carbamoyl or N-lower alkyl-carbamoyl, m and n are each 0 or 1, where m is 0 if n is 1 and m is 1 if n is 0,

dashed lines represent a single bond which is located between N-7 and C-8 if m is 0 and located between C-8 and N-9 if m is 1,

R₃ is lower alkyl or phenyl which are unsubstituted or in each case substituted by hydroxyl, lower alkoxy, amino, lower alkylamino or N,N-di-lower alkylamino and a) R₄ is hydrogen, amino, phenylamino, lower alkylamino, hydroxyl, phenoxy, lower alkoxy; an acyl radical of the part formula Z-C(=W)-, in which W is oxygen, sulfur or imino and Z is R°, R°-O- or an amino group of the formula R₇(R₈)N-, in which R° in each case is C₁-C₄alkyl, hydroxy-C₂-C₁₄alkyl, cyano-C₁-C₄alkyl, carboxy-C₁-C₄alkyl, C₁-C₄alkoxycarbonyl-C₁-C₄alkyl, C₃-C₇alkenyl or phenyl and R₇ and R₈ independently of one another are each hydrogen, lower alkyl, ω-amino-lower alkyl, lower alkylsulfonyl or phenyl; an aliphatic hydrocarbon radical having not more than 29 C atoms, which is substituted by halogen, amino, lower alkylamino, o-amino-lower alkylamino, lower alkanoylamino, benzoylamino, hydroxylamino, hydroxylimino, lower alkoxy-amino, phenyloxyamino, aminocyclohexyl-amino-, amino-phenyl-amino-, carbamoyl-amino, (N-lower alkyl-carbamoyl)amino, (N-[ω-amino-lower alkyl]-carbamoyl)-amino, (N-phenyl-carbamoyl)-amino, mercapto, lower alkylthio, thiocarbamoyl, thioureido, N-lower alkyl-thioureido, N-phenylthioureido, guanidino, N-lower alkyl-guanidino, carboxyl, lower alkoxycarbonyl, phenyloxycarbonyl, benzyloxycarbonyl, hydroxylaminocarbonyl, carbamoyl, amidino, cyano, hydroxyl, lower alkoxy, phenyloxy, aminocarbonyl-oxy, oxo, aminosulfonyl, lower alkylsulfonyl-amino, glycylamino, alanylamino, phenylalanylamino, prolylamino, valylamino, leucylamino, isoleucylamino, serylamino, threonylamino, cysteinylamino, methionylamino, tyrosylamino, tryptophanylamino, arginylamino, histidylamino, lysylamino, glutamylamino,

qlutaminylamino, asparagylamino, asparaginylamino or phenylglycylamino; benzyl;

2-phenyl-ethyl; 3-aminomethyl-benzyl; (1-hydroxy-cyclohex-1-yl)-methyl; (2-amino-3,5,5trimethyl-cyclopentyl)-methyl; 1-[N-(1-carboxy-2-phenyl-ethyl)-carbamoyl]-2-carbamoyl-eth-1-yl; 1-carbamoyl-1-phenyl-methyl; 1-carbamoyl-2-(4-hydroxy-phenyl)-eth-1-yl; 1carbamoyl-2-phenyl-eth-1-yl; 2-amino-1,2-diphenyl-eth-1-yl; 2-benzyloxycarbonyl-1carbamoyl-eth-1-yl; 3-benzyloxycarbonyl-1-carbamoyl-prop-1-yl; 1-adamantyl-2-aminoprop-1-yl; 1-adamantyl-1-amino-prop-2-yl; (2-furyl)-methyl; (2-tetrahydrofuryl)-methyl; 2pyrid-2-yl-ethyl; 2-piperidino-ethyl; 2-(morpholin-4-yl)-ethyl; 2-(3-indolyl)-ethyl; 2-(4imidazolyl)-ethyl; 1-carbamoyl-2-(β-indolyl)-eth-1-yl; 1-carbamoyl-2-imidazol-4-yl-eth-1-yl; 1-carbamoyl-2-indol-3-yl-eth-1-yl; 3-aminomethyl-oxetan-3-yl-methyl; 1-(acetoxy-imino)-1-(4-amino-2-oxa-1,3-diazol-5-yl)-methyl; 2-amino-cyclohex-1-yl; 3-amino-cyclohex-1-yl; 2aminomethyl-3,3,5-trimethyl-cyclopent-1-yl; 3-amino-adamantan-1-yl; 2-carbamoylbicyclo[2.2.1]hept-5-en-3-yl; 2-carbamoyl-cyclohex-1-yl; 9-amino-spiro[4.4]non-1-yl; 5amino-2-oxa-1,3-diazol-4-yl; 4-amino-thien-3-yl; 3-carbamoyl-5-(3-[2,4-dichloro-phenyl]-1oxo-prop-2-en-1-yl)-1,2-thiazol-4-yl; 3-carbamoyl-5-(3-[4-trifluoro-phenyl]-1-oxo-prop-2-en-1-yl)-1,2-thiazol-4-yl; 4-amino-2-(4-carboxy-butyl)-tetrahydrothiophen-3-yl; 3-amino-2-(4carboxy-butyl)-tetrahydrothiophen-4-yl; [1,2,5]oxadiazolo[3,4-b](6-amino-pyrazin-5-yl); 2,5'diacetyl-3-amino-thieno[2,3-b]thiophen-4'-yl or 3-amino-2,5'-dipivaloyl-thieno[2,3b)thiophen-4'-yl, and

R₅ independently of R₄, is as defined above for R₄, with the exception of hydrogen and an aliphatic hydrocarbon radical having not more than 29C atoms, which is substituted by hydroxyl, or

b) R_4 and R_5 together are 1,2-ethylene, propane-1,3-diyl, butane-1,4-diyl, pentane-1,5-diyl, 3-(3-amino-propionyl)-3-aza-pentane-1,5-diyl, 1-aminomethyl-butane-1,4-diyl, 1-hydroxy-

methyl-butane-1,4-diyl, 3-(2-amino-ethyl)-pentane-1,5-diyl, 3-aza-pentane-1,5-diyl or 3-(2-amino-ethyl)-3-aza-pentane-1,5-diyl, or a salt thereof:

Claim 3. A compound of the formula I according to Claim 2, in which q is 1-3 and

R₄ is hydrogen,
or a salt thereof.

Claim 19. A method of treating tumors which are responsive to the inhibition of p34^{cdc2}/cyclin B^{cdc13} kinase, comprising administering to a subject in need of such treatment a therapeutically effective amount of a compound of formula I according to claim 2, or a pharmaceutically acceptable salt thereof.

The Rejections

In the Final Rejection (Paper No. 10), the examiner entered these rejections:

- 1. Claims 2-4, 6, 14, and 16-19 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure (the enablement requirement).
- 2. Claims 2, 3, 14, 16, 18, and 19 under 35 U.S.C. § 112, first paragraph, as based on a specification which does not contain an adequate written description of the subject matter now claimed (the written description requirement).
- 3. Claims 2, 16, and 19 under 35 U.S.C. § 112, second paragraph, as indefinite.

- 4. Claims 2, 6, 14, 18, and 19 under 35 U.S.C. § 102(a) as anticipated by Mackman.¹
- 5. Claim 4 under 35 U.S.C. § 103(a) as unpatentable over Mackman.

In the Examiner's Answer (Paper No. 16), the examiner maintained rejection 2. predicated on the written description requirement; and rejection 3. predicated on indefiniteness to the extent that that rejection is applied against claim 19. All remaining rejections set forth in Paper No. 10 have been dropped.²

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 15); (3) the Examiner's Answer (Paper No. 16); and (4) the Final Rejection (Paper No. 10).

On consideration of the record, including the above-listed materials, we <u>affirm</u> the rejection of claims 2, 14, 16, 18, and 19 under 35 U.S.C. § 112, first paragraph (written description requirement). However, we <u>reverse</u> the rejection of claim 3 under

¹ U.S. Patent No. 5,866,702 issued to Mackman et al. (Mackman) on February 2, 1999.

The examiner sets forth the applicable rejections in section (10) of the Examiner's Answer (Paper No. 16) page 3, last paragraph; and page 4, first paragraph). The examiner expressly states that "the description issue and the art rejection are dropped" (<u>Id.</u>, page 2, last paragraph). Considering the Examiner's Answer in its entirety, we understand this to mean that: (1) the previously entered rejection based on the <u>enablement requirement</u> of 35 U.S.C. § 112, first paragraph, has been dropped; and (2) the previously entered rejections under 35 U.S.C. § 102(a) and 35 U.S.C. § 103(a) have also been dropped.

35 U.S.C. § 112, first paragraph (written description requirement). We also <u>reverse</u> the rejection of claim 19 under 35 U.S.C. § 112, second paragraph.

Written Description

We agree with the examiner's finding that claim 2 lacks adequate written descriptive support in the specification, as filed, for the subject matter now claimed where variable R₄ is an aliphatic hydrocarbon radical having not more than 29 carbon atoms which may be substituted, <u>inter alia</u>, by "mercapto." For reasons succinctly stated by the examiner (Paper No. 16, page 4), applicants' original disclosure of "thio" does not provide adequate support for the newly introduced term "mercapto."

In the Appeal Brief, applicants' sole argument on this point is that "mercapto" is supported by the original specification, page 8, line 13 (Paper No. 15, paragraph bridging pages 5 and 6). The argument lacks merit. As correctly found by the examiner, applicants' reference to "mercapto" at page 8, line 13, of the specification, is in a different context, i.e., that passage in the specification is discussing a group having the formula $R_7(R_8)N$ -. That passage is not discussing the substituent in question where variable R_4 is an aliphatic hydrocarbon radical having not more than 29 carbon atoms which may be substituted, inter alia, by "mercapto."

The rejection of claim 2 under 35 U.S.C. § 112, first paragraph, is <u>affirmed</u>. Claims 14, 16, 18, and 19 suffer the same infirmity as claim 2 and have not been argued separately. Therefore, claims 14, 16, 18, and 19 fall together with claim 2.

Claim 3, however, stands on different footing. This follows because, in claim 3, R₄ is hydrogen. This claim does not include the recitation of R₄ as "an aliphatic hydrocarbon radical having not more than 29 C atoms, which is substituted by . . . mercapto." In other words, claim 3 does not include the very recitation which gives rise to the examiner's rejection under 35 U.S.C. § 112, first paragraph (written description requirement). The examiner's position to the contrary, notwithstanding, the written description issue does not apply "equally" to claims 2, 3, 14, 16, 18, and 19 (Paper No. 16, section 7). The rejection of claim 3 under 35 U.S.C. § 112, first paragraph, as based on a specification which does not contain an adequate written description of the subject matter now claimed is reversed.

Indefiniteness

We disagree with the examiner's assessment of claim 19 under 35 U.S.C. § 112, second paragraph. In our judgment, the description of assays in the specification, pages 18 through 20, provides adequate guidance to any person skilled in the art for determining those tumors "which are responsive to the inhibition of p34^{cdc2}/cyclinB^{cdc13} kinase."

As stated in <u>In re Moore</u>, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971):

This first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed - not in a vacuum, but always in light of the teachings of the prior art and of the particular application

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disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. [footnote omitted]

Having considered claim 19 in light of the application disclosure, we believe that this claim does, in fact, "set out and circumscribe a particular area with a reasonable degree of precision and particularity."

The rejection of claim 19 under 35 U.S.C. § 112, second paragraph, for indefiniteness, is <u>reversed</u>.

Conclusion

In conclusion, for the reasons set forth in the body of this opinion, the rejection of claims 2, 14, 16, 18, and 19 under 35 U.S.C. § 112, first paragraph (written description requirement), is <u>affirmed</u>. However, the rejection of claim 3 under 35 U.S.C. § 112, first paragraph (written description requirement), is <u>reversed</u>. We also <u>reverse</u> the rejection of claim 19 under 35 U.S.C. § 112, second paragraph.

The examiner's decision is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Sherman D. Winters

Administrative Patent Judge

) BOARD OF PATENT

Eric Grimes)
Administrative Patent Judge) APPEALS AND

Lora M. Green

Administrative Patent Judge

) INTERFERENCES

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